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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/830,111	07/23/2001	Hideyuki Matsuda	1581/00265	3002

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 09/02/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/830,111	MATSUDA ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 June 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,7-14 and 17-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,7-10,12-14 and 17-20* is/are rejected.

7)☒ Claim(s) *11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

The amendment filed June 2, 2003 amending the specification to insert the sequence identifiers and replace the Sequence Listing, canceling claims 5, 6, 15 and 16, amending claims 1-4 and 13 has been entered.

The CRF filed June 2, 2003 contained errors. The Raw Sequence Listing Error Report was faxed to Applicants on June 6, 2003. In response thereto, Applicants twice filed a substitute Sequence Listing and CRF thereof on June 16, 2003 and July 2, 2003, respectively. The copies of the Sequence Listing and its CRF filed on June 16, 2003 and July 2, 2003 are identical. The current file copy of the Sequence Listing and the CRF is the one filed on July 2, 2003.

The Declaration under 37 C.F.R. 1.808 by Mr. Burton Amernick filed June 2, 2003 has been entered.

Claims 1-4, 7-14 and 17-20 are pending.

Specification

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825.

37 CFR 1.821(d) requires the use of assigned sequence identifier in all instances where the description or claims of a patent application discuss sequences.

The following are examples of incompliance where the sequence containing more than ten nucleotides is given without a sequence identifier: page 11, line 1.

Furthermore, 37 CFR 1.821(c) requires that the sequences disclosed in the specification be presented in the Sequence Listing. The current copy of the Sequence Listing contains only 2 sequences.

*Applicants are required to amend the specification by replacing the current Sequence Listing with a substitute Sequence Listing containing **all** sequences disclosed in the specification. Said substitute Sequence Listing must be accompanied by CRF and a statement that the paper and CRF copies are identical and do not introduce new matter.*

The specification is objected to because on page 17, line 16, it refers to Q_8 where it appears Q_{10} is intended.

Claim Objections

Claims 1 and 2 are objected to because of the following informalities:

Claim 1 is drawn to "An isolated or purified DNA selected from the group consisting of the following (a) and (b): a DNA having, ..." (emphasis added). "(a)" should be inserted after semicolon before "a DNA". Further, "; and" should be inserted

after "SEQ ID NO:1" before "(b)". It is suggested that "the following (a) and (b)" be deleted.

Claim 2 is drawn to "An isolated or purified protein selected from the group consisting of the following (a) and (b): (a) a protein having, ..." (emphasis added). Further, "; and" should be inserted after "SEQ ID NO:2" before "(b)". It is suggested that "the following (a) and (b)" be deleted.

Claim 2 recites "not less than 60%" where it appears "no less than 60%" is intended.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-4, 7-10, 12-14 and 17-20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a decaprenyl diphosphate synthase of SEQ ID NO:2 and a DNA encoding thereof, does not reasonably provide enablement for a decaprenyl diphosphate synthase having no less than 60% homology to SEQ ID NO:2 and a DNA encoding thereof and a DNA that hybridizes to SEQ ID NO:1 under stringent conditions comprising a wash with 0.5

xSSC, 6M urea and 0.4% SDS at 42°C, said DNA encoding decaprenyl diphosphate synthase. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, how to make the invention commensurate in scope with these claims.

Factors to be considered in determining whether undue experimentation is required, are summarized in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir. 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

Claim 1 is directed to a DNA encoding a decaprenyl diphosphate synthase that hybridizes to SEQ ID NO:1 under stringent conditions comprising a wash with 0.5 xSSC, 6M urea and 0.4% SDS at 42°C. The specification does not teach the sequences with which percent homology to SEQ ID NO:1 hybridize under said conditions. It appears that the recited conditions are low or medium stringency conditions. Claim 2 is directed a decaprenyl diphosphate synthase having "a homology of not less than 60%" to SEQ ID NO:2. Claim 3 is directed to a DNA encoding the protein of claim 2. Claims 4, 7-10, 12-14 and 17-20 depend on claims 1 or 3.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the extremely large number of decaprenyl diphosphate synthase enzymes and genes broadly encompassed by the claims. Since the amino acid sequence of a protein determines its structural and functional properties, predictability of which changes can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which amino acids in the protein's sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the proteins' structure relates to its function. However, in this case the disclosure is limited to the nucleotide and amino acid sequence of a single decaprenyl diphosphate synthase.

While recombinant and mutagenesis techniques are known, it is not routine in the art to screen for multiple substitutions or multiple modifications, as encompassed by the instant claims, and the positions within a protein's sequence where amino acid modifications can be made with a reasonable expectation of success in obtaining the desired activity/utility are limited in any protein and the result of such modifications is unpredictable. In addition, one skilled in the art would expect any tolerance to modification for a given protein to diminish with each further and additional modification, e.g. multiple substitutions.

The specification does not support the broad scope of the claims which encompass a decaprenyl diphosphate synthase and a DNA encoding thereof with unknown homology to the *Saitoella complicata* decaprenyl diphosphate synthase and a DNA encoding thereof because the specification does **not** establish: (A) regions of the protein structure which may be modified without effecting decaprenyl diphosphate synthase activity; (B) the general tolerance of decaprenyl diphosphate synthase to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any decaprenyl diphosphate synthase residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make the claimed invention in a manner reasonably correlated with the scope of the claims broadly including a great number of modifications in SEQ ID NO:1 and SEQ ID NO:2. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without such guidance the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> > (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 4, 7-9, 12 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Suzuki et al.

Suzuki et al. teach a gene (dps) encoding decaprenyl diphosphate synthase from *Schizosaccharomyces pombe*. They teach a vector and an *E. coli* cell comprising thereof. Said cell produces a 378 amino acid long decaprenyl diphosphate synthase having the sequence that is 42% identical to SEQ ID NO:2. Said cell also produces ubiquinone-10 (coenzyme Q_{10}). Absent the showing to the contrary, it is presumed that said gene hybridizes to SEQ ID NO:1 under stringent conditions comprising a wash with 0.5 xSSC, 6M urea and 0.4% SDS at 42°C.

Allowable Subject Matter

Claim 11 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed June 2, 2003 have been fully considered but they are not persuasive.

Applicants assert that the amendments to claims 1 and 2 have overcome the rejection under 112, 1st paragraph (Remarks, page 8). Applicants do not present their arguments to support the assertion.

With regard to the 102(b) rejection, Applicants argue that "this DNA does not hybridize with the DNA of SEQ ID NO:1" without presenting any supporting evidence. It is *a priori* unknown and the specification does not teach percent homology of a DNA that hybridizes to SEQ ID NO:1 under the recited stringent conditions.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner
August 29, 2003